

DEPARTMENT OF HEALTH AND HUMAN SERVICES

DMB

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Food and Drug Administration

[Docket No. 02N-0063]

Agency Emergency Processing Request Under OMB Review; Consumer Surveys on Food and Dietary Supplement Labeling Issues

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for emergency processing under the Paperwork Reduction Act of 1995 (the PRA). The proposed collection of information would consist of surveys to study consumers' understanding of labeling on conventional foods and dietary supplements as well as consumer practices, knowledge levels, and attitudes related to such labeling.

**DATES:** Submit written or electronic comments on, the collection of information by *[insert date 30 days after date of publication in the Federal Register]*.

**ADDRESSES:** Submit electronic comments on the collection of information to <http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm>. Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Peggy Schlosburg, Office of Information Resources Management (HFA-250); Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

**SUPPLEMENTARY INFORMATION:** FDA is requesting emergency processing of this proposed collection of information under section 3507(j) of the PRA (44 U.S.C. 3507(j) and 5 CFR 1320.13). The information is critical to the agency's mission of regulating food labeling and is needed prior to the expiration of the normal time periods for OMB clearance under the PRA regulations (5 CFR part 1320). The U.S. Constitution's first amendment impact on regulatory decisions on labeling necessitate prompt agency action to ensure that the constitutional rights of regulated entities are preserved. For this reason, the use of normal clearance procedures would be likely to prevent or disrupt this collection of information. Under section 903(d)(2)(C) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 393(d)(2)(C)), FDA is authorized to conduct research related to food labeling.

FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

### **Consumer Surveys on Food and Dietary Supplement Labeling Issues**

FDA is requesting OMB approval of consumer surveys to help FDA's Center for Food Safety and Applied Nutrition formulate decisions and policies affecting the labeling of conventional foods and dietary supplements. Determining how consumers are likely to interpret various kinds of claims, disclaimers, warnings, caution statements, and notice statements that might appear in labeling is critical to agency decisionmaking under the act and the first amendment. It is often necessary to test actual or proposed labeling statements in realistic situations with typical consumers to determine what these label statements are communicating to consumers.

FDA or its contractor will collect and use information gathered from telephone, mail, shopping mall intercept, and Internet surveys to evaluate how consumers understand and respond to existing label statements, label statements proposed by industry or consumers, and other label statements that are under consideration as part of FDA's policy development process. Potential respondents to the surveys will be individual consumers either randomly chosen to represent specified populations or randomly assigned to experimental treatment conditions to control for the effects of individual differences in the population on the interpretation of label statements. In all instances, FDA will strive to collect a representative sample of individuals from the overall population or from relevant population groups, as appropriate. FDA's general selection method will use stratification, with random sampling within the strata, to achieve representativeness for both overall populations and sensitive subpopulations, such as at-risk individuals or user segments. In the rare cases where geography is a limiting factor, FDA will use population-based cluster sampling to limit government expense while preserving the statistical properties of the sample.

Respondents will provide background information and respond to package labels that contain the variations of label statements to be tested. Measures will include both self-reported comprehension and acceptance as well as direct behavioral measures of consumer use and understanding of the package labeling.

FDA will use the information from the surveys in evaluating regulatory and policy options with respect to labeling. The agency often lacks empirical data about how consumers understand and respond to statements they might see in product labeling. The information gathered from such surveys can be used to test consumer comprehension and behavioral impact of various label statements and formats, and to identify the existing distribution of behavior, knowledge, and attitudes in the population that provides the context for understanding such statements. The surveys will help FDA assess consumer reactions to existing and proposed label statements.

FDA estimates the burden of this collection of information as follows:

**TABLE 1 .-ESTIMATED ANNUAL REPORTING BURDEN'**

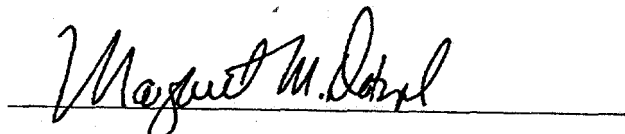
Type of Survey	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Mail questionnaire .....	1,000	1	1,000	1	1,000
Telephone survey .....	2,000	1	2,000	.5	1,000
Internet or cable survey .....	4,000	1	4,000	.5	2,000
<b>Total</b> .....					<b>4,000</b>

'There are no capital costs or operating and maintenance costs associated with this collection of information.

'These estimates are based on the expected number of respondents necessary to obtain a statistically significant representation of important consumer segments (e.g., users of relevant regulated products, at-risk population groups), and the number of labeling options that may need to be tested.

Dated: 2-15-02

February 15, 2002.



Margaret M. Dotzel,  
Associate Commissioner for Policy.

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